NATIONAL MARROW DONOR PROGRAM®

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October 30, 2014

LCDR Christopher Steele
Office of Naval Research
Code 34 – Warfighter Performance
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-13-1-0039 between the Office of Naval Research and the National Marrow Donor Program

Dear LCDR. Steele:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of July 1, 2014 to September 30, 2014.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention at 612-362-3403 or at cabler@nmdp.org.

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Contracts Manager

Enclosure: Quarterly Report with SF298

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation: Create a platform that facilitates multicenter collaboration and data management.

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Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-13-1-0039

DEVELOPMENT OF MEDICAL TECHNOLOGY FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY PERFORMANCE / TECHNICAL REPORT

FOR

JULY 01, 2014 to SEPTEMBER 30, 2014

PERIOD 7

Office of Naval Research

And

The National Marrow Donor Program
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QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

July 01, 2014 through September 30, 2014

TABLE OF CONTENTS

IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians

IIA.1 Task 1: *Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.*

Period 7 Activity:

- Continued the review of the process for the distribution of the medical countermeasure G-CSF (Neupogen) following a mass casualty radiological incident with the Association of State and Territorial Health Officials on the joint ASTHO – CDC – RITN
- A meeting was held in Alexandria, VA with state and city public health officials from the National Capitol Region, New York (NYC), Illinois (Chicago) and California (Los Angeles)
- During the meeting existing plans and exercises were reviewed then a scenario of how to best distribute the medication was discussed for ½ a day with each city/state then issues and gaps were discussed as a group

IIA.1 Task 2: *GCSF in Radiation Exposure – This task is closed.*

IIA.1 Task 3: *Patient Assessment Guidelines and System Enhancements – This task is closed*

IIA 1 Task 4: *National Data Collection Model – This task is closed.*

IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2 Task 1: *Ensure NMDP maintains effective plans to continue critical facility and staff-related functions as a result of operations interruption events.*

Period 7 Activity:

- No activity this period.

IIA.2 Task 2: *Sibling Typing Standard Operating Procedures – This task is closed*

IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.

IIA.3 Task 1: *I.S. Disaster Recovery – This task is closed.*

IIA.3 Task 2: *Critical Facility and Staff Related Functions – This task is closed.*

IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.

IIB.1 Task 1: *Expand the genetic diversity of the Registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies.*

Period 7 Activity:

2-Step Recruitment at Live Drive Registration:

- The 2-Step Activation Phase Two Pilot ran from March 28 through August 28, 2013. Phase Two included an online activation channel, in addition to the Phase One channels of phone and text activation.
- Additional information is under analysis from an email outreach to those who did not activate their membership during the pilot period.

IIB.1 Task 2: *Evaluate HLA-DRB1 High Res typing – This task is closed.*

IIB.1 Task 3: *Evaluate HLA-C Typing of Donors – This task is closed*

IIB.1 Task 4: *Evaluate the suitability of buccal swabs as a method to collect DNA samples to HLA type casualties and potential related donors in contingency situations, and to obtain research samples.*

Period 7 Activity:

Frozen Buccal Swab Storage Study:

- The study will compare swabs stored at room temperature and -30°C, for quality of DNA, quantity of DNA, and high resolution HLA characterization, at selected time points over multiple years.

- Baseline testing of room temperature and frozen swabs has been completed.
  - The sample cohort consisted of freshly collected room temperature samples, and frozen samples that were collected and stored at -30°C for a range of 4-7 months, from 30 previously HLA typed consenting volunteers.
  - HLA testing of the samples used a three-pronged approach covering various methodologies including long range amplification Next Generation Sequencing (NGS) typing methodology, Sanger based sequencing (SBT), and Sequence Specific Oligonucleotide (SSO).
  - Detailed analysis of all the data is underway. A preliminary look at some of the data show comparable DNA quantity and quality measures.
    - DNA quantity of the room temperature swabs compared to the frozen swabs showed no substantial differences in the concentrations of DNA [RT: 12.6 ng/ul (±9.0), Frz: 17.4 ng/ul (±16.0)].
    - DNA quality comparisons (subjective measure, scale of 1-4) also indicated no substantial differences between room temperature and frozen samples [RT: 2.7 (±1.1), Frz: 2.0 (±0.9)].
- More in-depth analysis will continue, as well as the evaluation of all HLA typing results.

IIB 1 Task 5: *Evaluate the factors of donor utilization and speed of search process after strategic upgrading of selected adult volunteer donors.*

Period 7 Activity:

- No activity this period.

IIB 1 Task 6: *Maintain a comprehensive quality control program.*

Period 7 Activity:

Genomic DNA Swabs as a Quality Control sample type:

- During this quarter, purified DNA extracted from existing blood aliquots of 233 QC volunteer blood donors was received by the Biorepository for use in the NMDP blind buccal swab QC program.
- Aliquots from these samples were shipped for high resolution confirmatory typing of HLA-A, B, C, DRB1, DRBX, DQA1, DQB1, DPA1, and DPB1.
- Nine purified DNA QC Masters were validated and added to the regular blind buccal QC program, increasing the number of

purified DNA QC Masters to 19; 219 masters await validation prior to inclusion.

- Existing volunteer QC blood donors with insufficient inventory were drawn and sent for purified DNA extraction.

Cord Blood Unit Quality Control Samples:

- During this quarter, high resolution typing on 22 new CBU masters was validated. These new CBU masters were incorporated into the cord QC program, adding 10 unique A alleles, 16 unique B alleles, 3 unique C alleles, 5 unique DR alleles, and 4 unique DPB1 alleles, as well as providing previously lacking QC CBU allelic coverage at DRBX, DQA1, and DPA1.

IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.

IIB 2 Task 1: *Ongoing collection of primary data for validation and storage in the Registry database.*

Period 7 Activity:

- No activity this period.

IIB 2 Task 2: *Validation of Logic of Primary Data – This task is closed.*

IIB 2 Task 3: *Reinterpretation of Primary Data – This Task has been merged with Task IIB2.4.*

IIB 2 Task 4: *Interpretation of the primary data into genotype lists and integration into matching algorithm to optimize placement of donors onto patient searches.*

Period 7 Activity:

- No activity this period.

IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.

IIB.3 Task 1: *Incorporate HLA allele and haplotype frequencies into matching algorithm.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 2: *Continue to enhance the allele and haplotype frequency data to include additional loci and increased resolution for ethnic groups with input from consultants with expertise in population genetics.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 3: *Cord Blood and Adult Donor Matching Benchmarks and Registry Modeling.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 4: *Couple haplotype prediction methodology with donor demographic data to target recruitment to areas populated by individuals with underrepresented HLA phenotypes.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 5: *Develop a bioinformatics web site for frequency information.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 6: *Use NMDP's expert Search Strategy Advisors as resources to further improve the matching algorithm and donor/cord blood identification software applications with the goal to maximize the ability of the software to identify the best donors/cords for each patient.*

Period 7 Activity:

- No activity this period.

IIB 3 Task 7: *Population Genetics – This task was merged with Task IIB3.2*

IIB 3 Task 8: *Haplotype Matching – This task was merged with Task IIB3.2*

IIB 3 Task 9: *Global Haplotype/Benchmark – This task was merged with Task IIB3.3*

IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

IIB.4 Task 1: *Expand Network Communications – This task is closed.*

IIB.4 Task 2: *Conduct a study of random patient search simulations to test the efficacy of centralized contingency management.*

Period 7 Activity:

- This period the NMDP initiated a project evaluating the patient match rate of HLA-DPB1 T-cell Epitope (TCE) donors for patients with 10/10 donor matches. Recent research has demonstrated potential benefit for matching at the DPB1 TCE for patients given the luxury of multiple donors to select. New patient preliminary searches entered into the NMDP with DPB1 typing were evaluated for eligibility criteria. Searches meeting the criteria were evaluated for existing DPB1 TCE donor matches or if no existing matches, HLA typing was performed to identify a match (max 10 donors per patient). During this period 183 searches were enrolled and 280 donors were HLA typed. The results to date were submitted as an abstract to the 2015 ASBMT/CIBMTR Tandem meeting. The study will continue to accrue additional patients to increase in the next quarter.

IIB.4 Task 3: *Benchmarking Analysis – This task is closed*

IIB.4 Task 4: *Expand Capabilities of Collection and Apheresis Centers – This task is closed.*

IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.

IIC.1 Task 1: *Continue to evaluate HLA disparity and impact on HSC transplantation by adding selected pairs to the Donor/Recipient Pair project utilizing sample selection criteria that optimize the new data generated by the typing project.*

Period 7 Activity:

In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies. Presence/absence typing of 16 Killer Immunoglobulin-Like Receptor (KIR) loci (2DL1-5, 2DS1-5, 3DL1-3, 3DS1, 2DP1 and 3DP1) has been included.

- Auditing of sample group (SG) 32, consisting of 402 single cord blood transplants, 299 double cord blood transplants and 843 donor/recipient transplants, HLA and KIR has continued.
- SG 33 containing of 2272 adult donor/recipient pairs, 92 single cord blood/recipient pairs and 171 double cord blood triplets came to a close on September 30, 2014.
- SG 34 containing 1145 related donor/recipient pairs came to a close on September 30, 2014.
- HLA data loading into the data base continued this quarter and KIR data loading began and will continue into next quarter.

Most clinical association studies of KIR have analyzed at presence/absence resolution for each gene. Although the region has long been known to be both allelically and structurally diverse, the extent of copy number variation (CNV) has only started to be clarified. CNV data has the potential to improve, association studies by reducing confounding factors and increasing haplotypic resolution.

- Copy number variation typing of minority samples and samples not passing linkage analysis is still ongoing.

Current HLA matching guidelines for unrelated HCT recommend avoidance of mismatches within the Antigen Binding Domain (ABD). This recommendation is based on the hypothesis that amino acid differences outside the ABD are not immunogenic. The ABD allo-reactivity assessment project aims to provide insight impact of mismatching outside of the ABD.

- Four DRB1*14:01:01/14:54 containing haplotypes were identified and 334 samples were typed at A, B, C, DRB1/3/4/5, DQB1 and DPB1.
- 57 donors were approached to participate in the study.
- 19 donors consented and had samples drawn for peripheral blood mononuclear cell collection.
- Analysis of the samples will occur in the next quarter.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.

IIC.2 Task 1: *Continue to develop typing protocols for non-HLA immunogenetic loci, development of a lab network, enhancement of database to capture non-HLA data and continue analyses to evaluate genetic diversity in the transplant population.*

Period 7 Activity:

- During the past quarter we performed SNP typing on a cohort of 1000 transplantation pairs in support of the CIBMTR study IB12-02 on genetic ancestry.

IIC 2 Task 2: *Related Pairs Research Repository – This task is closed.*

IIC 2 Task 3: *CIBMTR Integration – This task is closed.*

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1 Task 1: *Conduct observational research and interventional clinical trials.*

Period 7 Activity:

- No activity this period.

IID.1 Task 2: *Research with NMDP Donors – This task was merged with IID1.1.*

IID.1 Task 3:

Expand support for immunobiology research, statistical genetics and clinical research studies under CIBMTR Immunobiology Working Committee.

Period 7 Activity:

- No activity this period.

ACRONYM LIST

AABB	American Association of Blood Banks	HRSA	Health Resources and Services Administration
AFA	African American	HSC	Hematopoietic Stem Cell
AGNIS	A Growable Network Information System	IBWC	Immunobiology Working Committee
ABD	Antigen Binding Domain	ICRHER	International Consortium for Research on Health Effects of Radiation
AML	Acute Myelogenous Leukemia	IDM	Infectious Disease Markers
API	Asian Pacific Islander	IHWG	International Histocompatibility Working Group
AQP	Ancestry Questionnaire Project	IPR	Immunobiology Project Results
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IND	Investigational New Drug
ASBMT	American Society for Blood and Marrow Transplantation	IS	Information Services
ASHI	American Society for Histocompatibility and Immunogenetics	IT	Information Technology
ASTHO	Association of State and Territorial Health Officials	IRB	Institutional Review Board
B-LCLs	B-Lymphoblastoid Cell Lines	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BARDA	Biomedical Advanced Research and Development Authority	KIR	Killer Immunoglobulin-like Receptor
BBMT	Biology of Blood and Marrow Transplant	LCL	Lymphoblastoid Cell Line
BCP	Business Continuity Plan	MDACC	MD Anderson Cancer Center
BCPeX	Business Continuity Plan Exercise	MDS	Myelodysplastic Syndrome
BMCC	Bone Marrow Coordinating Center	MHC	Major Histocompatibility Complex
BMDW	Bone Marrow Donors Worldwide	MICA	MHC Class I-Like Molecule, Chain A
BMT	Bone Marrow Transplantation	MICB	MHC Class I-Like Molecule, Chain B
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MKE	Milwaukee
BODI	Business Objects Data Integrator	MRD	Minimal Residual Disease
BRT	Basic Radiation Training	MSKCC	Memorial Sloan-Kettering Cancer Center

C&A	Certification and Accreditation	MSP	Minneapolis
CAU	Caucasian	MUD	Matched Unrelated Donor
CBMTG	Canadian Blood and Marrow Transplant Group	NAC	Nuclear Accident Committee
CBB	Cord Blood Bank	NACCHO	National Association of County & City Health Officials
CBC	Congressional Black Caucus	NCBI	National Center for Biotechnology Information
CBS	Canadian Blood Service	NCBM	National Conference of Black Mayors
CBU	Cord Blood Unit	NARR	National Alliance for Radiation Readiness
CDA	Clinical Document Architecture	NCI	National Cancer Institute
CDE	Common Data Element	NDMS	National Disaster Medical System
CFU	Colony Forming Unit	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CGI	Common Gateway Interface	NGS	Next Generation Sequencing
CHORI	Children's Hospital of Oakland Research Institute	NHLBI	National Heart Lung and Blood Institute
CHTC	Certified Hematopoeitic Transplant Coordinator	NIH	National Institutes of Health
CIBMTR®	Center for International Blood & Marrow Transplant Research	NIMA	Non-Inherited Maternal Antigen
CIT	CIBMTR Information Technology	NIMS	National Incident Management System
CLIA	Clinical Laboratory Improvement Amendment	NK	Natural Killer
CMCR	Centers for Medical Countermeasures Against Radiation	NLE	National Level Exercise
CME	Continuing Medical Education	NMDP®	National Marrow Donor Program
CMF	Community Matching Funds	NRP	National Response Plan
CMV	Cytomegalovirus	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CNV	Copy Number Variation	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
COG	Children's Oncology Group	OIT	Office of Information Technology
CREG	Cross Reactive Groups	OMB	Office of Management and Budget
CSS	Center Support Services	ONR	Office of Naval Research

CT	Confirmatory Testing	OTTR	Organ Transplant Tracking Record
CTA	Clinical Trial Application	P2P	Peer-to-Peer
		PBMC	Peripheral Blood Mononuclear Cells
DC	Donor Center	PBSC	Peripheral Blood Stem Cell
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	PCR	Polymerase Chain Reaction
DIY	Do it yourself	PHE	Public Health Emergencies
DKMS	Deutsche Knochenmarkspenderdatei	PSA	Public Service Announcement
DMSO	Dimethylsulphoxide	QC	Quality control
DoD	Department of Defense	RCC	Renal Cell Carcinoma
DNA	Deoxyribonucleic Acid	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DR	Disaster Recovery	REAC/TS	Radiation Emergency Assistance Center/Training Site
D/R	Donor/Recipient	RED	Radiological Exposure Device
DSTU	Draft Standard for Trial Use	REST	Representational State Transfer
EBMT	European Group for Blood and Marrow Transplantation	RFP	Request for Proposal
ED	Emergency Department	RFQ	Request for Quotation
EDC	Electronic Data Capture	RG	Recruitment Group
EFI	European Federation of Immunogenetics	RITN	Radiation Injury Treatment Network
EM	Expectation Maximization	SBT	Sequence Based Typing
EMDIS	European Marrow Donor Information System	SCTOD	Stem Cell Therapeutics Outcome Database
ENS	Emergency Notification System	SG	Sample Group
ERSI	Environment Remote Sensing Institute	SHF	Synthetic Haplotype Frequency
FACT	Federation for the Accreditation of Cellular Therapy	SLCBB	St. Louis Cord Blood Bank
FBI	Federal Bureau of Investigation	SLW	STAR Link® Web
FDA	Food and Drug Administration	SSA	Search Strategy Advice
FDR	Fund Drive Request	SSO	Sequence Specific Oligonucleotides
FEMA	Federal Emergency Management Agency	SSP	Sequence Specific Primers
FLOCK	Flow Cytometry Analysis Component	SSOP	Sequence Specific Oligonucleotide Probes

FP	Filter Paper	STAR®	Search, Tracking and Registry
Fst	Fixation Index	SW	Buccal Swab
GETS	Government Emergency Telecommunications Service	TC	Transplant Center
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	TED	Transplant Essential Data
GIS	Geographic Information System	TIDES	Toolkit for Immunogenomic Data Exchange and Storage
GS	General Services	TNC	Total Nucleated Cell
GTR	Genetic Testing Registry	TP	Time Point
GvHD	Graft vs Host Disease	TSA	Transportation Security Agency
HCS®	HealthCare Standard	UCBT	Umbilical Cord Blood Transplant
HCT	Hematopoietic Cell Transplantation	UCSF	University of California – San Francisco
HEPP	Hospital Emergency Preparedness Program	USID	Unique System Identifier
HHQ	Health History Questionnaire	USIDNet	U.S. Immunodeficiencies Network
HHS	Health and Human Services	UI	User Interface
HIPAA	Health Insurance Portability and Accountability Act	UML	Unified Modeling Language
HIS	Hispanic	URD	Unrelated Donor
HLA	Human Leukocyte Antigen	WGA	Whole Genome Amplification
HML	Histoimmunogenetics Mark-up Language	WMDA	World Marrow Donor Association
HR	High Resolution	WU	Work-up